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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/632,947

07/31/2003

Alastair Hodges

104978-172

4975

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7590

04/07/2009

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EXAMINER

OLSEN, KAJ K

ART UNIT

PAPER NUMBER

1795

NOTIFICATION DATE

DELIVERY MODE

04/07/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No. 10/632,947	Applicant(s) HODGES ET AL.	
	Examiner KAJ K. OLSEN	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 14-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/15/2008 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(f) he did not himself invent the subject matter sought to be patented.

3. Claims 1-7 and 14-20 rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

4. Applicant has significantly amended the claims to make the subject matter of the claims have priority back to applications PCT/AU99/46585, PCT/AU96/00724, and PCT/AU96/00723. However, 37 CFR 1.45(c) states that each inventor listed on an application must have made a contribution to at least one claim of an application (MPEP 605.07). Because the claims now consist of limitations having priority back to these earlier applications and because Ron Chatelier was never considered to be an inventor of these earlier applications and, it is unclear how Mr. Chatelier can be still considered to be an inventor of the current application.

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5. Claims 1-6, 14, 16, and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Diebold et al (USP 5,437,999) with evidence from WO 99/46585 (hereafter "WO '585").

6. Diebold discloses a device for detecting the presence or absence of a redox reactive analyte (glucose) in an aqueous sample (blood), that comprises an electrochemical cell having one or more walls, a sensing chamber 49, first and second electrodes (32, 46) where the these electrodes are mounted to opposite sides of an electrically resistive material (34, 43) (fig. 3 and 4 and col. 7, l. 8 - col. 8, l. 11). The edge of cutouts 35 and 44 define an aperture extending through the electrically resistive material. Said aperture also defining a sidewall of the electrochemical cell, a first electrode area, and a second electrode area. With respect to the second aperture being for admitting sample into the sensing chamber, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. Diebold also discloses a second aperture (36 or 47) as well as a reagent disposed onto a wall of the electrochemical cell where the reagent includes glucose oxidase, which can react directly with the analyte glucose to produce an electrical signal indicative of the presence or absence of the analyte (col. 10, ll. 14-60 and col. 12, l. 63 - col. 13, l. 8). With respect to the quantity of reagent being applied, because Diebold discloses at least one experiment being performed with the reagent, the quantity of reagent is sufficient for a single test.

7. With respect to the choice of electrode materials, see col. 6, ll. 25-34 and col. 7, ll. 35-46.

8. With respect to the presence of a heating element, WO '585 evidences that an AC voltage applied to the working and counter electrodes could function as a heating element for the sensor. See p. 7, ll. 14-16. Hence, because Diebold already discloses the presence of a working and

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counter electrode (see discussion above), then the electrodes of Diebold could inherently function as a heating element if an AC potential were applied to these electrodes. Furthermore, claim 16 defines that the set forth heating element can be a broadly defined “exothermic substance contained within the sensing chamber”. Any number of the materials of Diebold would be exothermic in the sense that when they are burned, they produce an exothermic reaction (i.e. metals and organic constituents are all exothermic upon combustion). See the various polymers, organic reagents, electrode materials, etc. Because these various materials would be exothermic upon combustion, then they read on the broadly defined heating element of claim 16. Although these exothermic materials differ significantly from the exothermic materials of the present invention, applicant hasn’t defined these exothermic materials with any specificity to read away from Diebold. The examiner notes that the applicant's defined these exothermic materials in much greater detail in claim 1 of USP 6,475,360.

9. With respect to the set forth interface, see col. 7, ll. 25-27 and col. 8, ll. 3-6.

10. With respect to whether the interface transmits a voltage or current, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. However, the interface of Diebold communicates both as a voltage is applied to the interface and a current is read back from that same interface. See col. 12, l. 63 - col. 13, l. 8.

11. With respect to Diebold being a thin-layer electrochemical cell, the device of Diebold would read on the defined “thin” giving the claim language its broadest reasonable interpretation.

12. Claims 14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/18464 (hereafter “WO ‘464”).

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13. As discussed in previous office actions, WO '464 anticipates all the limitations of claim 1. However, because all the claim limitations of claim 1 has 35 U.S.C. 112 support back to PCT/AU96/007724, WO '464 is no longer prior art against claim 1. However, PCT/AU96/007724 does not provide 35 U.S.C. 112 support back to claims 14-16 as this subject matter only has support back to PCT/AU99/00152. Hence, WO '464 is still qualifies as prior art with respect to these claims under 35 U.S.C. 102(b). With respect to claims 14 and 16, these claims are anticipated over the use of AC voltage or the broadly defined "exothermic material" for the same reasons as Diebold was utilized above.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold in view of Nankai et al (USP 5,120,420).

18. With respect to claim 7, Diebold set forth all the limitations of the claim, but did not explicitly recite the use of a reference electrode in addition to the first and second electrodes. Nankai teaches in an alternate electrochemical cell that a three-electrode embodiment of a sensor (by adding a reference electrode) is more accurate than a two-electrode embodiment of the sensor. See col. 13, ll. 6-12. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Nankai for the sensor of Diebold so as to provide a more accurate electrochemical sensor.

19. With respect to claim 17, Diebold set forth all the limitations of the claim, but did not specify the distance between the first and second electrode. Nankai teaches that the spacer width that defines the capillary passage for the sensor should not be too large because that would require larger samples and would impede the capillary wicking of fluid into the chamber. Nankai taught that the spacer should be preferably down to 50 microns and more preferably down to 100 microns. See col. 12, ll. 43-54. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Nankai for the sensor of Diebold such that the sensor requires less sample and facilitates capillary wicking of

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the fluid. It is noted that Diebold is also interested in minimizing the amount of sample required for analysis. See the abstract and col. 12, ll. 39-42. Because the width of the measuring chamber in Diebold is the same thing as the spacing between the first and second electrodes, the incorporation of the spacing from Nankai for the measuring chamber of Diebold would result in a distance between the two electrodes of less than 100 microns.

20. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold in view of Graves (USP 5,342,498).

21. Diebold set forth all the limitations of the claims, but did not explicitly teach the use of a heater for heating the sample. Graves teaches in an alternate electrochemical sensor that the addition of a heating element allows the temperature of the sensor and analyte to be precisely controlled (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Graves for the sensor of Diebold in order to provide a narrower sensor temperature range, which allows for more accurate measurements. With respect to the heater of Graves being “in a region of the sensing chamber” (claim 14), this new limitation includes heating elements that are merely “adjacent to the sensing chamber” (claim 15). Because the heater of Graves would be adjacent to any sensing chamber, it would thereby be in a region of the sensing chamber as defined by the claims.

22. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO ‘464 in view of Graves.

23. WO ‘464 set forth all the limitations of the claims, but did not explicitly teach the use of a heater for heating the sample. Graves teaches in an alternate electrochemical sensor that the addition of a heating element allows the temperature of the sensor and analyte to be precisely

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controlled (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Graves for the sensor of WO '464 in order to provide a narrower sensor temperature range, which allows for more accurate measurements. With respect to the heater of Graves being "in a region of the sensing chamber" (claim 14), this new limitation includes heating elements that are merely "adjacent to the sensing chamber" (claim 15). Because the heater of Graves would be adjacent to any sensing chamber, it would thereby be in a region of the sensing chamber as defined by the claims.

Double Patenting

24. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

25. Claims 1-7 and 14-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6-8, 11, 12, 14-20, 22, 24, 27-30, and 42 of U.S. Patent No. 6,638,415 in view of Diebold.

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26. See the discussion of this double patenting rejection in the various preceding office actions.

Response to Arguments

27. With respect to the arguments of 12/15/2008, the examiner agrees that reference WO '464 can no longer be utilized as a teaching against the majority of the claims in view of the amendment. The examiner has withdrawn the use of WO '464 against all of the claims except for claims 14-16 for the reasons set forth in the rejection above.

28. With respect to claims 14 and 15 applicant urges that Graves fails to teach or suggest a heating element located in a region of the sensing chamber. In particular, the heater of Graves is disposed throughout the entire board and is configured to heat several sensors and not a chamber. However, it is unclear of the significance of this as the primary teachings of Diebold or WO '464 already set forth a sensing chamber. If it is obvious to control the temperature of sensors by heating in general, then it would have been obvious to control the temperature of sensors having a sensing chamber as well. The reasons for controlling the temperature as set forth by Graves would be relevant whether a sensing chamber were being utilized or not. Applicant further urges that it would not have been obvious to one of ordinary skill in the art to utilize the entire heater of Graves in a region of a sensing chamber of WO '464. This argument is unpersuasive for a number of reasons. First, there is nothing in the claims that would require the heater to be located only at a point adjacent to the sensing chamber. Claim 14 requires the heating element be "located in a region of the sensing chamber" and a heater that is located over the entire substrate of the sensor is also included in a region of the sensing chamber as well. Claim 15

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requires the bridge element “effective to concentrate a heating effect adjacent the sensing chamber”. Again, a heater over the entire substrate of the sensor of Diebold or WO ‘464 would concentrate heat over everything including the sensing chambers of Diebold and WO ‘464.

Hence, this heater of Graves would meet this limitation even if the heating element concentrated heater over other locations as well. There is nothing in the claims that requires the heater to be located in only one particular location of the cell. Second, the reason Graves heats its entire sensor is presumably because Graves has multiple sensors scattered over the entire substrate (see fig. 1). If the measurement cell included only a single measurement chamber located only in a particular spot of the substrate, then one possessing ordinary skill in the art would recognize that it is unnecessary to heat an entire electrochemical cell substrate. If heating is not desired or needed over the entire substrate, then it would have been obvious to not include a heating element in those locations. “If a feature of reference structure is not desired, it would seem a matter of obvious choice to eliminate it and the function it serves.” *In re Larson, Russler, and Meldahl*, 144 USPQ 347.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAJ K. OLSEN whose telephone number is (571)272-1344. The examiner can normally be reached on M-F 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kaj K Olsen/
Primary Examiner, Art Unit 1795
April 3, 2009